



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Tornier
Mrs. Severine Bonneton
Regulatory Affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint-Ismier Cedex
FRANCE

Re: K100142

Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: May 3, 2010
Received: May 5, 2010

Dear Mrs. Bonneton:

This letter corrects our substantially equivalent letter of May 6, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100142

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

Cemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Uncemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non-repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non-repairable rotator cuff-tear. The humeral components are for non-cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.


Prescription-Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number _____

K100142

K100142 #1/4

TORNIER

MAY - 5 2010

Implants Chirurgicaux

Summary of Safety and Effectiveness information
510(k) Premarket Notification – Aequalis Reversed Shoulder Prosthesis

Date: April 29th, 2010

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *Aequalis Reversed Shoulder Prosthesis*
Common name: Total-Shoulder System and Hemi-Shoulder System
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Shoulder, Hemi-, Humeral, Metallic uncemented

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

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4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: KWS, HSD

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316, K061439, K081059.

Aequalis Reversed Fracture Shoulder System, TORNIER SA, K082120.

Delta Xtend Reverse Shoulder System, DEPUY, K062250, K071379, K091751.

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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

K100142 #2/4

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6) Device description

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.

The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists of:

- the addition of humeral stems with hydroxylapatite coating,
- the addition of 2 sizes of metaphyses with hydroxylapatite coating,
- the update of the *Aequalis Reversed Shoulder Prosthesis* indications for use.

7) Materials

The stems are manufactured from titanium alloy. The metaphyses are manufactured from cobalt-chromium alloy and ultra high molecular weight polyethylene (UHMWPE).

The hydroxylapatite coating conforms to ASTM standard F 1185. The coating is performed by BioCoat, Inc. according to their Master File MAF-339.

8) Indications for use

Cemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the *Aequalis Reversed* prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of a *Aequalis Reversed* prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of *Aequalis Reversed* range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the *Aequalis Reversed* prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.



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Uncemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. The humeral components are for non-cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.

When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

9) Summary of technological characteristics

Main features or system characteristics		Aequalis Reversed (new components)	Aequalis Reversed	Aequalis Reversed Fracture	Delta Xtend Reverse Shoulder
Materials	Humeral stem	Ti6Al4V	CoCr	Ti6Al4V	CoCr + UHMWPE
	Metaphysis	CoCr + UHMWPE	CoCr + UHMWPE	-	
Coating material	Humeral part	Hydroxylapatite	uncoated	Hydroxylapatite	Hydroxylapatite or uncoated
Size	Humeral stem	4 diameters 4 lengths	4 diameters 4 lengths	5 diameters 4 lengths	5 diameters 9 lengths
	Metaphysis	2 sizes:36 or 42 mm	2 sizes:36 or 42 mm	40 mm	2 sizes
Stem / metaphysis type		Modular	Modular	Monobloc	Monobloc or modular
Method of fixation Humeral component		uncemented	cemented	partially cemented	cemented or uncemented
Terminal sterilization		Gamma	Gamma	Gamma	Gamma
Manufacturer		Tornier	Tornier	Tornier	DePuy
K-number		K100142	K030941, K041873, K050316, K061439, K081059	K082120	K062250, K071379, K091751

The technical characteristics (materials, design and sizing) of the new components of the Aequalis Reversed Shoulder Prosthesis are similar or identical to the predicate devices.



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K100142 #9/4

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10) Non-clinical testing

Non-clinical testing was not necessary to determinate substantial equivalence between the new uncemented stems and new uncemented metaphysis of the Aequalis Reversed Shoulder Prosthesis and the cited predicate devices:

- The design of the new components of the Aequalis Reversed Shoulder Prosthesis (uncemented stems and uncemented metaphyses) is identical to the design of predicate Aequalis Reversed Shoulder Prosthesis (K030941, K041873, K050316, K061439, and K081059) except for the addition of an HA coating.
- The raw material of the new components of the Aequalis Reversed Shoulder Prosthesis (uncemented stems and uncemented metaphyses) is identical to the raw material of predicates Aequalis Reversed Fracture Shoulder Prosthesis (K082120) and Delta Xtend (K062250, K071379, and K091751).
- The coating material of the new components of the Aequalis Reversed Shoulder Prosthesis (uncemented stems and uncemented metaphyses) is identical to the coating material of the predicate Aequalis Reversed Fracture Shoulder Prosthesis (K082120).
- The fixation method of the new humeral components of the Aequalis Reversed Shoulder Prosthesis is identical to the fixation method of the predicates Aequalis Reversed Fracture Shoulder Prosthesis (K082120) and Delta Xtend (K062250, K071379, and K091751).

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the new components of the Aequalis Reversed Shoulder Prosthesis to the cleared components of the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The new components of the Aequalis Reversed Shoulder Prosthesis are compared to the predicate devices.
- The new components of the Aequalis Reversed Shoulder Prosthesis have the same intended use as the cleared predicate.
- Major technological characteristics are equivalent between the new components of the Aequalis Reversed Shoulder Prosthesis and the predicate devices:
 - Equivalence of general features
 - Equivalent means of fixation
 - Equivalent materials
 - Equivalent surgical technique.

Therefore, in the light of the above information, the new components of the Aequalis Reversed Shoulder Prosthesis are found to be equivalent to the predicate devices.



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